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Newark / Philadelphia

February 24, 2022

VIA ECF
Honorable Edward S. Kiel, U.S.M.J.
United States District Court, District of New Jersey
United States Post Office & Courthouse
Federal Square, Courtroom 8
Newark, New Jersey 07101

Re: ***Status Conference***
United States ex rel. Silbersher v. Janssen Biotech, et al.,
Civil Action No. 19-12107 (KM-ESK)

Dear Judge Kiel:

The parties in the above-captioned matter have met and conferred in advance of the Status Conference with the Court on February 25, 2022. The parties would like to raise the following items for discussion with the Court at the Status Conference.

I. Proposed Schedule

The parties have agreed on the below proposed schedule.

Event/Deadline	**Date**
Parties Serve Revised Requests for Production ("RFPs")	March 25, 2022
Defendants' Answer to Second Amended Complaint	March 25, 2022
Parties Serve Responses & Objections ("R&Os") to Revised RFPs	One month from Service of Revised RFPs, or April 25, 2022
Rule 26(f) Conference	Two weeks from service of R&Os, or May 9, 2022
Rule 26(f) Report (Joint Discovery Plan)	One week from Rule 26(f) Conference, or May 16, 2022
Status Conference	1 week from filing of Rule 26(f) Report, or week of May 23, 2022

The parties have agreed that phased discovery is appropriate and will continue to meet and confer regarding longer-term case scheduling in connection with the Rule 26(f) Conference. The parties expect to provide the Court with an update regarding additional dates and deadlines at the next status conference.[1]

[1] Relator proposes that all fact discovery should be completed nine (9) months from the date of the next Status Conference; expert discovery completed within four (4) months from the close of fact

II. Request and Production of Third-Party Confidential Information

As the Court is aware, preliminary discovery in this case had focused on certain material produced, received, or exchanged in connection with the underlying patent infringement litigation (the "ANDA Litigation").[2] Some of the requested material either contained or implicated non-party confidential material protected by a Stipulated Discovery Confidentiality Order in that case (the "ANDA Confidentiality Order"). *See BTG Int'l Ltd. v. Amneal Pharms. LLC*, No. 2:15-cv-5909 (KM-JBC), Dkt. 172. Defendants have attempted to obtain consent from the relevant non-parties to re-produce to Relator the protected, confidential material exchanged in the ANDA Litigation. All of the relevant non-parties, including the generic drug manufacturer defendants from the ANDA Litigation, have been provided with the Stipulated Confidentiality Order (Dkt. 162) (the "Confidentiality Order") that the Court entered in this case.

At the time of the November 8, 2021 joint status update, Defendants had received consent from six non-party generic drug companies.[3] Defendants have produced documents and information implicating those non-parties' confidential information except where those non-parties' confidential information is potentially intermingled with non-consenting generic drug companies' confidential information. Since the November 8, 2021 status update, Defendants have obtained the consent of a

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discovery; and Rule 56 and *Daubert* motions filed within two (2) months from the close of expert discovery; and trial within 18 to 24 months from the next Status Conference.

Defendants believe it is premature to project a case schedule prior to the exchange of revised document requests and responses. The previous document requests to Defendants were a joint effort on behalf of Relator and numerous antitrust plaintiffs. The new requests and responses will help define the scope of the remaining case and facilitate discussion for the parties' Rule 26(f) Conference.

[2] The underlying patent infringement litigation refers to the following matters: *BTG Int'l Ltd. et al. v. Amneal Pharm. LLC, et al.*, 15-cv-05909 (D.N.J.) (lead consolidated case); *BTG Int'l Ltd. et al. v. Amerigen Pharm., Inc. et al.*, 16-cv-2449 (D.N.J.) (consolidated with *Amneal* per ECF No. 16); *BTG Int'l Ltd. et al. v. Teva Pharm. USA, Inc.*, 17-cv-6435 (D.N.J.) (consolidated with *Amneal* per ECF No. 23); *BTG Int'l Ltd. et al. v. Qilu Pharm. Co., Ltd. et al.*, 18-cv-16521 (D.N.J.); *BTG Int'l Ltd. et al. v. MSN Pharm. Inc. et al.*, 18-cv-2372 (D.N.J.); and *BTG Int'l Ltd. et al. v. Glenmark Pharm., Inc., et al.*, 16-cv-03743 (D.N.J.).

[3] Those entities include: (1) Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Limited; (2) Wockhardt Bio AG, Wockhardt Ltd., and Wockhardt USA LLC; (3) MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, MSN Laboratories Private Limited, and MSN Pharmaceuticals Inc.; (4) Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd.; (5) Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries Ltd., Actavis Laboratories FL, Inc., Actavis Pharma, Inc., and Actavis, Inc., and (6) Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York, LLC.

seventh non-party generic drug company.[4] Defendants are in the process of finalizing the consent of an eighth non-party and expect to secure that consent in the near future. One non-party generic drug company has declined to consent to the re-production of its ANDA Litigation productions but has consented to the re-production of certain ANDA Litigation-related materials.[5] The remaining four non-party generic drug companies have declined consent entirely.[6]

Relator believes that the Court's existing Order dated July 8, 2021 (Dkt. 158, at ¶ 1(c)(1)) already obligates Defendants to produce these documents from the underlying patent litigation and PTAB proceeding. Moreover, the Court's Confidentiality Order provides that if a "Producing Party"[7] objects to the production of its confidential information, then the "party who received the [discovery] demand" must produce the documents unless the objecting party advises it will "seek prompt judicial relief" by the "date specified for disclosure." (Dkt. 175, at ¶ 10) None of the objecting generic companies have done so.

Defendants disagree and believe that the ANDA Confidentiality Order under which Defendants received the non-party confidential information does not contain a carve-out for confidential materials requested through lawful process. The non-consenting third parties are not parties to this action, and if their documents that were produced under protections in another action are to be produced by Defendants to Relator here, it should be only after Relator makes a motion, on notice to them. Although Defendants have sought those non-parties' consent and were successful in many such instances, others questioned the relevancy of their highly confidential documents in another action to which they are not parties. This Court should not resolve those issues without

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[4] The seventh entity is Citron Pharma LLC ("Citron"). Because discovery has been stayed, Defendants have not yet produced any confidential Citron material.

[5] Specifically, Apotex Corp. and Apotex Inc. have consented to the re-production of materials that relate to outside counsel's retention of copies of the pleadings or other papers filed with the Court or served in the course of the litigation, the deposition transcripts, the deposition exhibits, and the trial record.

[6] Those entities include: (1) Mylan, Inc.; (2) Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.; (3) Hikma Pharmaceuticals, PLC, Hikma Pharmaceuticals, LLC, and West-Ward Pharmaceutical Corp. (a subsidiary of Hikma); and (4) Sun Pharmaceuticals Industries, Ltd. and Sun Pharmaceuticals Industries, Inc.

[7] The Confidentiality Order broadly defines a "Producing Party" to include the generic companies in the underlying patent and PTAB litigation: "[P]ersons or entities producing information and designating documents or information as Protected Information under this Discovery Confidentiality Order—including without limitation the parties to this Action, their representatives, agents, experts and consultants, all third parties providing discovery in this action, and all other interested persons with actual or constructive notice of this Protective Order." (Dkt. 175, at ¶ C)

hearing from them. Moreover, Defendants should not be put in the middle of two possibly conflicting orders.

Accordingly, the parties have agreed that it is now appropriate to seek the Court's guidance regarding the re-production of non-consenting third-party generic drug companies' confidential material.

III. Modification of the Confidentiality Order

Currently, the Confidentiality Order has two levels of confidentiality protection, including "Confidential," and "Highly Confidential." (Dkt. 175, at ¶¶ 2(A)-(B)) Documents that were previously produced as part of the ANDA Litigation and previously designated in that litigation as "Highly Confidential–Outside Counsel's Eyes Only [OCEO]" retain that designation under the terms of the instant Confidentiality Order (Dkt. 175, at ¶¶ 1(B), (G)) Documents that are designated as Confidential and Highly Confidential may be shared with representatives of each of the parties. (Dkt. 175, at ¶¶ 3(F) & 4(A))

Relator believes that it is necessary for the efficient prosecution of the *qui tam* that he be permitted access to all documents produced in this action, including Highly Confidential-OCEO documents. Relator further believes that there is no potential competitive injury to the generic companies, because he is an individual and not involved in the sale or manufacture of pharmaceutical products. Accordingly, Relator seeks the Court's guidance regarding amendment of the Confidentiality Order to provide that he may review Highly Confidential-OCEO documents, *i.e.*, amend the first sentence of Paragraph 5 of the Confidentiality Order such that Highly Confidential-OCEO documents may be made "available and accessible only to those persons listed in paragraphs 3(A)-(F) . . ." (instead of "3(A)-(E)" as currently written).

Defendants object to any change at this time, and stress again that Relator will be able to see any new documents sought through discovery in this case. The restriction relates only to the documents previously produced under an OCEO designation in the ANDA Litigation, implicating the rights of those non-parties that produced them. Modification of the Confidentiality Order will only further complicate efforts to re-produce non-party material from the ANDA Litigation, particularly as certain non-parties previously consented to the re-production of that material on the condition that such material was designated as Highly Confidential – OCEO. The Confidentiality Order reserves the rights of the parties to contest any use of the Highly Confidential – OCEO designation to the extent a party believes the designation was, or is, incorrect and/or improper. (Dkt. 175 ¶ 1(G)) Relator may utilize this provision to challenge a Highly Confidential – OCEO designation for any document that he wishes to review. Regardless, a motion, with notice to the non-parties whose confidential information is at issue, is the proper vehicle by which to raise this issue. Only then can the Court consider the views of all interested stakeholders, including those of the non-parties whose information was either produced under the Highly Confidential – OCEO designation or is now being sought

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without the protection of the Highly Confidential – OCEO designation, contrary to the Confidentiality Order that they were previously provided.

Respectfully yours,

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